



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 720, 721, and 723

[EPA-HQ-OPPT-2014-0650; FRL-5605-02-OCSPP]

RIN 2070-AJ94

Significant New Uses of Chemical Substances; Updates to the Hazard Communication Program and Regulatory Framework; Minor Amendments to Reporting Requirements for Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is amending the regulations governing significant new uses of chemical substances under the Toxic Substances Control Act (TSCA) to align with revisions that were made to the Occupational Safety and Health Administration (OSHA) Hazard Communications Standard (HCS) and changes to the OSHA Respiratory Protection Standard and the National Institute for Occupational Safety and Health (NIOSH) respirator certification requirements for the respiratory protection of workers from exposure to chemicals. In addition, EPA is amending the regulations governing Significant New Use Rules (SNURs) to address issues that have been identified by EPA and raised by stakeholders through public comments. EPA is also making a minor change to reporting requirements for premanufacture notices (PMNs) and other TSCA notifications. EPA expects these changes to have minimal impact on the costs and burdens of compliance, while updating the significant new use reporting requirements to assist in addressing any potential risks to human health and the environment.

DATES: This final rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: The docket for this action, identified by docket identification (ID)

number EPA-HQ-OPPT-2014-0650, is available at <https://www.regulations.gov> or in-person at the EPA Docket Center (EPA/DC). Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is open to visitors by appointment only. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Tyler Lloyd, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-4016; email address: lloyd.tyler@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (defined by TSCA to include import), process, or use chemical substances subject to regulations in 40 CFR part 720, 721, or 723. The following list of North American Industry Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Chemical Manufacturers (NAICS code 325).
- Petroleum and Coal Products (NAICS code 324).
- Merchant Wholesalers, Nondurable Goods (NAICS code 424).

If you have any questions regarding the applicability of this action, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine whether a use of a chemical substance is a “significant new use.” EPA is required to issue its determination through promulgation of a final rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Such rules are called “significant new use rules” (SNURs). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before manufacturing or processing a chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). TSCA section 5(a)(1)(B) requires persons to notify EPA at least 90 days before manufacturing a new chemical substance for commercial purposes (under TSCA, manufacture includes import). TSCA section 3(11) defines a “new chemical substance” as any substance that is not on the TSCA Inventory of Chemical Substances compiled by EPA under TSCA section 8(b).

C. What action is the Agency taking?

EPA is finalizing amendments to the general requirements for SNURs in 40 CFR Part 721, Significant New Uses of Chemical Substances that were proposed in 2016 (81 FR 49598, July 16, 2016) (FRL 9944-47) (Ref. 1). Based on public comments received on proposed changes to 40 CFR 721.63, EPA will move certain language which was proposed at 40 CFR 721.63(a)(1) and (4) to new paragraphs at 40 CFR 721.63(a)(7) and (a)(8), respectively, to ensure the new provisions only apply to SNURs issued after the finalization of this rule (see Unit III.A). With the exception of amendments proposed at 40 CFR 721.63(a)(1) and (4), all other amendments are being finalized as proposed. Most of the changes relate to the standard significant new uses for new chemical SNURs identified in 40 CFR 721 subpart B, which EPA cross-references in individual SNURs in subpart E. Other changes are procedural changes to the general provisions in subpart A that apply to all SNURs. EPA also clarified in the preamble of the proposed rule some definitions contained in 40 CFR part 721 and is making a minor change to reporting requirements for TSCA section 5 notices in 40 CFR parts 720.38, 720.45 and 723.50.

D. Why is the Agency taking this action?

Based on changes that have occurred for respiratory protection requirements, codified in NIOSH regulations at 42 CFR part 84 and the OSHA standard at 29 CFR 1910.134, EPA is making changes to 40 CFR 721.63. In addition, based on the updates to 29 CFR 1910.1200, OSHA's modified Hazard Communication Standard (HCS) published March 26, 2012 (77 FR 17574) (Ref. 2), EPA is making changes to 40 CFR 721.72. EPA is also amending 40 CFR part 721 subparts A and B and clarifying definitions contained in 40 CFR part 721. EPA is making these changes and clarifications based on its experience in issuing and administering over 2,800 SNURs. Many of the changes are based on public comments received by EPA in the course of proposing and issuing SNURs, and questions or suggestions from the public regarding current SNUR requirements, such as considering a hierarchy of controls before using personal protective equipment to control exposures, clarifying the meaning of certain uses under 40 CFR 721.80(j), allowing for removal in wastewater treatment when computing estimated surface water concentrations according to 40 CFR 721.91, and revising the *bona fide* procedure in 40 CFR 721.11 to include coverage of situations where the significant new use terms are confidential.

E. What are the estimated incremental impacts of this action?

There will be a minor increase in the overall compliance burden and cost due to the modified requirements in 40 CFR parts 720, 721, and 723. The modified SNUR requirements will be compatible with the current hazard communication requirements under 29 CFR 1910.1200 and the respiratory protection requirements at 42 CFR Part 84 and 29 CFR 1910.134. The new paragraphs at 40 CFR 721.63(a)(7) and (8) will only apply to SNURs proposed after this final rule and are aligned with current industry practice. The modified SNUR requirements at 40 CFR 721.72 will also allow, but not require, persons subject to a SNUR that has been previously issued to use the updated requirements of 40 CFR 721.72.

The economic analysis for this final rule (Ref. 3) estimates that the amendments for new chemical SNURs and section 5 notices would result in a combined total first year burden and

cost of 1,585 hours and \$94,731, respectively. The total steady state increase cost is \$54,029 per year. On a per unit basis, the rule would impose startup costs ranging from \$0 to \$74.89 per new chemical SNUR, with incremental steady states costs ranging from \$0 to \$137.18.

II. Background

A. What did EPA propose?

On July 16, 2016 (Ref. 1), EPA proposed amendments to the regulations governing significant new uses of chemical substances under TSCA to align these regulations with revisions to the OSHA HCS, which are cross referenced. EPA further proposed the July 2016 amendments to align with changes to the OSHA Respiratory Protection Standard and the NIOSH respirator certification requirements for the respiratory protection of workers from exposure to chemicals. EPA also proposed revising the regulations governing SNURs, based on issues that have been identified by EPA and raised by stakeholders through the public comment process. Additionally, EPA proposed making a minor change to reporting requirements for premanufacture notices (PMNs) and other TSCA section 5 notices.

B. How did the Lautenberg Act amend TSCA Section 5?

Enacted on June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act) (Pub. L. 114-182) amended several sections of TSCA, including section 5. Among other changes, the Lautenberg Act added a new paragraph to TSCA section (5)(a)(3) titled “Review and Determination”, which obligates EPA to review and issue a determination on each notice received under section 5(a)(1) within the applicable review period. As amended by the Lautenberg Act, EPA is also now required to issue an order pursuant to TSCA section 5(e)(1) when it makes a determination under TSCA section 5(a)(3)(B) that either: (1) The information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance; (2) In the absence of sufficient information, the chemical substance may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially

exposed or susceptible subpopulation identified as relevant by EPA; or (3) The chemical substance is or will be produced in substantial quantities and may either enter the environment in substantial quantities or result in significant or substantial human exposure. While these amendments impact EPA's review of significant new use notices (SNUNs), the Lautenberg Act did not affect the amendments EPA proposed on July 16, 2016 (81 FR 4959) (Ref. 1), which EPA is now finalizing.

C. How are the SNUR regulations structured?

The manner in which the different subparts of 40 CFR part 721 are applied to new chemical SNURs and existing chemical SNURs is summarized in Table 1. EPA typically utilizes subparts B, C, and D when issuing new chemical SNURs for certain chemical substances that have undergone PMN review. Other SNURs, including existing chemical SNURs, may be issued for chemical substances either not on the TSCA Inventory or for those on the TSCA Inventory that typically have not undergone PMN review. In issuing existing chemical SNURs, EPA does not use subpart B or D but may apply the standard recordkeeping requirements in subpart C. The general requirements of subpart A apply to all SNURs unless these specific requirements are modified in the significant new use requirement section for a specific chemical substance listed in subpart E. Finally, Subpart E lists significant new use and recordkeeping requirements for new and existing chemical substances.

Table 1. Subparts used for New Chemical SNURs and Other Chemical SNURs.

Regulation in 40 CFR	New Chemical SNURs	Other Chemical SNURs
Subpart A. General Provisions (§§ 721.1 through 721.47)	X	X
Subpart B. Certain Significant New Uses (§§ 721.50 through 721.91)		
§ 721.63. Protection in the Workplace	X	
§ 721.72. Hazard Communication Program	X	
§ 721.80. Industrial, Commercial, and Consumer Activities	X	
§ 721.85. Disposal	X	
§ 721.90. Release to water	X	
§ 721.91. Concentration of estimated surface water concentrations: Instructions	X	
Subpart C. Recordkeeping Requirements (§§721.100 through	X	X

721.125)		
Subpart D. Expedited Process for issuing Significant New Use Rules for Selected Chemical Substances and Limitation or Revocation of Selected Significant New Use Rules (§§721.160 – 721.185)	X	
Subpart E. Significant New Uses for Specific Chemical Substances (§§ 721.225 through 721.10960)* ⁺	X	X

*Revised for each published SNUR.

⁺This figure is current as of May 1, 2022.

EPA is making substantive changes and clarifications to language in Subparts A and B of 40 CFR 721. The changes to Subpart A will affect all SNURs. The changes in Subpart B may affect some previously issued new chemical SNURs already in subpart E and will affect future new chemical SNURs issued using the changed terms in Subpart B. Unit III describes each change and how these changes may affect previously issued SNURs, as well as SNURs issued after this rule becomes effective. Not all of the previously issued new chemical SNURs will be affected by the changes in Subpart B. For example, as described in the economic analysis for this final rule (Ref. 3) and according to the EPA Chemical Data Report (CDR) for Reporting Year 2015, 107 chemicals were reported in commerce and subject to new chemical SNURS. Only 18 of the 107 SNURs contained provisions for worker protection and/or hazard communication. In March 2012, OSHA modified its Hazard Communication Standard (HCS) to conform to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS). OSHA's March 2012 regulatory amendments sought to enhance the effectiveness of the HCS by ensuring employees are apprised of the chemical hazards to which they may be exposed and reducing incidents of chemical-related occupational illnesses and injuries (Ref. 2). The GHS is an internationally harmonized system for classifying chemical hazards and developing labels and safety data sheets (SDS). The GHS further acts as a set of criteria and provisions that regulatory authorities can incorporate into existing systems or use to develop new systems.

The GHS utilizes a building block approach, which allows a regulatory authority to implement certain provisions that are appropriate for its sphere of regulation. The GHS includes the regulatory components, or building blocks, that might be needed for classification and the labeling requirements for chemicals in the workplace, transport, pesticides, and consumer

products. The 2012 amendments OSHA made to the HCS adopted certain sections of the GHS that were appropriate for OSHA's regulatory sector. The building block approach also gives regulatory agencies the authority to select which classification criteria and provisions to adopt. For example, OSHA adopted the classification criteria and provisions for labels and SDSs, because the current HCS covers these elements. As described in Unit III, EPA is adopting some of the GHS criteria for hazard communication pertaining to aquatic toxicity.

D. Did EPA receive public comments on the proposed rule?

EPA received 18 public comments on the proposed rule. Commenters included potentially affected businesses, trade associations, environmental and public health advocacy groups, and other Federal agencies. In this preamble, EPA has responded to many of the significant comments relevant to the proposed rule; however, the more comprehensive version of EPA's response to comments related to this final action can be found in the Response to Comments document (Ref. 4). The Response to Comment document summarizes all the comments relevant to the proposal and EPA's response to those comments. In the Response to Public Comments document, EPA also discusses any changes to and clarifications from the proposed rule.

III. Overview of the Final Rule

This final rule is based on the July 2016 proposal and consideration of the public comments received on the proposed rule.

As a result of changes to OSHA and NIOSH requirements, and other issues identified through EPA's experience issuing and administering SNURs, EPA is making several changes to the SNUR regulations in subparts A and B. The following sections describe the changes and the reasons for the changes.

A. Changes to 40 CFR 721.63, Protection in the Workplace.

Based on changes that have occurred in respiratory protection requirements since 1989, per the NIOSH regulation at 42 CFR part 84 and the OSHA standard at 29 CFR 1910.134, EPA

is making changes to 40 CFR 721.63. In June 1995, NIOSH updated and modernized its regulation for testing and certifying non-powered, air-purifying, and particulate-filter respirators (42 CFR part 84). The 42 CFR part 84 respirators have met a higher certification test than older respirators previously certified under 30 CFR part 11 and provide increased worker protection (Ref. 5). Because the 42 CFR part 84 test criteria simulate worst-case respirator use, NIOSH has encouraged discontinuing the use of particulate respirators certified under 30 CFR part 11 and switching to particulate respirators certified under 42 CFR part 84. However, non-powered particulate respirators that were approved under 30 CFR part 11 using the “old” labeling were allowed to be manufactured and sold until July 10, 1998. Specifically, distributors who purchased 30 CFR part 11 particulate filters and respirators prior to July 10, 1998, are able to sell them as "certified" until inventories of these products are depleted. Users who purchased such particulate filters and respirators from these distributors will be able to use them until their inventories are depleted or until the end of the shelf life or service life of these products.

Additionally, in January 1998, OSHA's revised Respiratory Protection Standard (29 CFR 1910.134) replaced the respiratory protection standards adopted by OSHA in 1971 (Ref. 6). Subsequently, in August 2006, OSHA announced that it modified its Respiratory Protection Standard (29 CFR 1910.134) by adding definitions as well as maximum use concentration (MUC) and assigned protection factor (APF) requirements to 29 CFR 1910.134 (Ref. 7). Due to these changes, the respirators currently listed in 40 CFR 721.63 may no longer meet the current NIOSH/OSHA criteria for respirator selection and use.

EPA is updating language pertaining to respiratory protection requirements listed in 40 CFR 721.63(a)(4), (a)(5), and (a)(6) to be consistent with both OSHA and NIOSH requirements. In 40 CFR 721.63(a)(4), which requires that respirators be used in accordance with 30 CFR part 11, EPA is replacing the reference to 30 CFR part 11 with a reference to 42 CFR part 84 to incorporate the most updated NIOSH regulation for testing and certifying respirators. Most manufacturers and processors are already subject to and complying with 42 CFR part 84. This

change will apply to all previously issued SNURs that contain significant new use requirements pertaining to respiratory protection by clarifying manufacturers and processors subject to current SNURs can follow updated respiratory protection requirements without triggering a SNUN requirement. The updated language will also be included in the issuance of new SNURs as appropriate.

EPA is also updating NIOSH-certified respirator language in 40 CFR 721.63(a)(5). At the time of the proposal, EPA had been incorporating the updated NIOSH-certified respirator language in newly issued SNURs rather than referencing the respirator language currently listed in 40 CFR 721.63(a)(5). EPA has continued citing the new respirator language in SNURs issued since this rule was proposed in July 2016 (81 FR 49598). The finalized provisions to 40 CFR 721.63(a)(5) will standardize the use of the updated NIOSH-certified respirator language and allow EPA to cross-reference the language for new chemical SNURs rather than on an individual basis.

EPA has included language that allows any person subject to SNURs with older respirator requirements in 40 CFR 721.63(a)(5) already cited in subpart E to continue using older-style respirators in order to avoid the triggering of a SNUN requirement. These fifteen older respirators are listed in 40 CFR 721.63(a)(5)(i) through (xv). EPA also includes language in 40 CFR 721.63(a)(5) that would allow any person subject to the older respirator requirements in 40 CFR 721.63(a)(5)(i) through (xv) to use an equivalent respirator under the newer requirements, provided that the APF of the new respirator is equal to or greater than the respirator cited in subpart E. EPA has included in the public docket a chart comparing the APF of the respirator classes in the current regulations with the previous corresponding respirator requirements that can be consulted in order to determine availability of suitable substitutes (Ref. 8). The amendment to 40 CFR 721.63(a)(6) also updates language for the airborne form of a chemical substance applicable to the respiratory protection requirements in 40 CFR 721.63(a)(4). EPA will cite this language when issuing new SNURs.

EPA is also revising 40 CFR 721.63 to add language that would make it a significant new use not to implement a hierarchy of controls to protect workers. This revision will require any person subject to an applicable SNUR to determine and use appropriate engineering and administrative controls before using personal protective equipment (PPE) for worker protection, similar to the requirements in OSHA standards at 29 CFR 1910.134(a)(1) and guidance in Appendix B to subpart I of 29 CFR 1910.

This change is being made in part due to comments received on recently promulgated SNURs. Some of these comments identified the industrial hygiene “hierarchy of controls” approach for workplace health and safety and argued that persons subject to SNURs should follow the OSHA standards requiring the use of controls that are higher in the hierarchy of controls before requiring employees to use personal protective equipment (PPE). In final SNURs published on June 26, 2013 (78 FR 38210) (FRL-9390-6) (Ref. 9), EPA responded to the comments, agreeing that a hierarchy of controls should be applied, and that PPE should be the last option in controlling exposures. Where engineering and administrative controls are not feasible or are insufficient to protect exposed workers, persons who are subject to a SNUR must follow any applicable PPE requirements or submit a SNUN to EPA. Since June 26, 2013, new chemical SNURs containing significant new uses related to lack of PPE for workers have included the same language requiring consideration and implementation of engineering controls and administrative controls where feasible. These requirements to consider engineering and administrative controls are based on and consistent with the OSHA requirements at 29 CFR 1910.134(a)(1).

In the July 2016 proposal (81 FR 49598), EPA proposed revising 40 CFR 721.63(a)(1) and 40 CFR 721.63(a)(4) to add language requiring consideration and use of engineering and administrative controls where feasible before PPE for worker protection. This change would have affected SNURs issued after this rule became effective in addition to previously issued SNURs that incorporate references to worker protection standards at 40 CFR 721.63(a)(1) and 40

CFR 721.63(a)(4). However, based on public comments, EPA has decided to move the language that was proposed at 40 CFR 721.63(a)(1) and 40 CFR 721.63(a)(4) to new paragraphs 40 CFR 721.63(a)(7) and 40 CFR 721.63(a)(8), respectively. These new paragraphs will not affect previously issued SNURs but rather, will only be applicable to SNURs issued or amended after this rule becomes effective. While EPA is not updating the language referenced by many existing SNURs, EPA continues to affirm that a hierarchy of controls should be applied, and that PPE should be the last option in controlling exposures. Additionally, EPA believes that most companies are already following a hierarchy of controls as required by OSHA regulations. EPA's response to public comments on the hierarchy of control language can be found in the Response to Comment document for this rule (Ref. 4).

B. Changes to 40 CFR 721.72, Hazard Communication Program.

Based on the changes to 29 CFR 1910.1200, OSHA's modified HCS, EPA is making changes to 40 CFR 721.72. In March 2012, OSHA modified its HCS to conform to the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS). OSHA's March 2012 regulatory amendments sought to enhance the effectiveness of the HCS by ensuring that employees are apprised of the chemical hazards to which they may be exposed and reducing incidents of chemical-related occupational illnesses and injuries (Ref. 2). Modifications to the HCS include revised criteria for classification of chemical hazards; revised labeling provisions that include requirements for use of standardized signal words, pictograms, hazard statements, and precautionary statements; a specified format for safety data sheets; and related revisions to definitions of terms used in the HCS and requirements for employee training on labels and safety data sheets (Ref. 2).

Under EPA's current regulations, when SNURs are issued with a citation to 40 CFR 721.72 in subpart E for a chemical substance, it is considered a significant new use if the company does not develop a written hazard communication program for the substance in the workplace. Paragraphs (a) through (h) of 40 CFR 721.72 can be cited in subpart E as elements

that must be included in the hazard communication program. Manufacturers and processors subject to a SNUR in subpart E for a chemical substance can rely on an existing hazard communication program, such as one established under the OSHA HCS or one based on GHS recommendations, to comply with this significant new use requirement to the extent the hazard communication program contains elements cited for that SNUR from 40 CFR 721.72 paragraphs (a) through (h).

EPA is adding new paragraphs (i) and (j) to 40 CFR 721.72 that it will use when imposing hazard communication requirements for SNURs issued after this rule becomes effective. The new paragraph (i) will require that a written hazard communication program be developed and implemented for the substance in each workplace in accordance with OSHA HCS 29 CFR 1910.1200.

This approach will maintain consistency in compliance for any person subject to TSCA and OSHA regulations for the same activity. By cross-referencing the OSHA HCS EPA should minimize duplication of requirements and minimize potential confusion that additional obligations are being created. In addition, any amendments to the OSHA HCS will be automatically encapsulated without EPA having to amend its own regulations. This approach is also consistent with the requirement for EPA to coordinate with other federal executive departments and agencies under TSCA section 9(d) to impose “the least burdens of duplicative requirements on those subject to the chapter and for other purposes.”

The new paragraph (j) describes specific statements and other warnings that could be incorporated in SNURs for substances identified in subpart E. The specific statements and warnings that could be required would be based on EPA’s risk assessment of the chemical substance and would be consistent with the OSHA HCS and GHS recommendations.

EPA expects that, whenever the statements in paragraphs (g), (h), and (j) are required and the determinations for the SNUR are published, manufacturers and processors subject to the SNUR will also consider if they trigger any other corresponding hazard communication under

the OSHA HCS requirements or under GHS recommendations. Any hazard and/or precautionary statements required by the SNUR will include a minimum set of hazard warnings. EPA may also propose individual SNURs or issue section 5(e) SNURs under 40 CFR 721.160 using other specific statements, signal words, symbols, hazard category, and pictograms as hazard communication requirements.

EPA is updating 40 CFR 721.72 paragraphs (a) through (h) to be consistent with both OSHA requirements and GHS recommendations. These changes apply to individual SNURs in subpart E issued before the effective date of this final rule as described in the next two paragraphs. EPA is making changes to 40 CFR 721.72 paragraphs (a), (c), and (d) to change using the term “material safety data sheet” (MSDS) to “safety data sheet” (SDS) and allow easily accessible electronic versions or other alternatives to maintaining paper copies of the SDS. These changes apply to any previously issued SNUR in subpart E that cites these paragraphs. EPA is also adding new hazard and precautionary statements, listed in 40 CFR 721.72 paragraphs (g) and (h), to make this provision consistent with statements under the OSHA HCS requirements and the GHS recommendations. While the previously issued SNUR precautionary and hazard statements will remain applicable solely for previously issued SNURs, EPA has also identified which of the new statements can be used as alternatives for the previously issued precautionary and hazard statements. Manufacturers and processors subject to a previously issued SNUR will have the option to use the prior precautionary and hazard statements or use the new alternative statements that are consistent with the OSHA HCS requirements or GHS recommendations to comply with the SNUR.

EPA is also including language which allows any person subject to a previously issued SNUR containing requirements for 40 CFR 721.72 paragraphs (a) through (h) to comply with those requirements by following the requirements of 40 CFR 721.72 paragraph (i), which will be applied to SNURs issued after this final rule, and using any statements specified for that substance in the 40 CFR 721.72 paragraphs (g) or (h). For example, a person currently subject to

a SNUR citing the requirement to establish a hazard communication program as described in 40 CFR part 721.72 paragraphs (a) through (f) and the requirement for using a hazard statement in paragraph (g)(1)(iii), central nervous system effects, could comply by taking the following steps: That person could establish a hazard communication program according to the requirements in paragraph (i) and use the hazard statement in paragraph (g)(1)(iii), “central nervous system effects,” or the alternative hazard statement (g)(1)(xi), “may cause damage to the central nervous system through prolonged or repeated exposure.”

EPA recommends using a Chemical Abstracts Service (CAS) number to identify the chemical substance in an SDS whenever possible. EPA makes this recommendation because CAS numbers are widely used by industry to provide a unique, unambiguous identifier for chemical substances. Only when a CAS number is not available should a different unique numerical identifier be used. Because of variations in naming conventions for chemical substances, using CAS numbers makes it easier for the regulated community to accurately identify and report chemical identities. For example, upon importation of a chemical substance, if the chemical substance is being identified to assure compliance with regulatory requirements, providing the most specific CAS number is the most efficient and clear way to ensure this. The changes for SNUR hazard communications requirements concerning how to identify chemical substances are consistent with OSHA regulations.

C. Clarification of the use of 40 CFR 721.80, Industrial Commercial and Consumer Activities.

EPA is also clarifying the significant new use for new chemical SNURs described at 40 CFR 721.80(j), which identifies as a significant new use as “Use other than as described in the premanufacture notice referenced in subpart E of this part for the substance.” EPA is not changing the language of 721.80(j). Instead, EPA is clarifying how it identifies a significant new use that meet the criteria in 721.80(j) for individual SNURs. When EPA issues a SNUR using the designation at 40 CFR 721.80(j) in subpart E for a chemical substance and that use described in the premanufacture notice is claimed as confidential, EPA cites 40 CFR 721.80(j). See Unit III.E

for a discussion of how manufacturers and processors subject to a SNUR with a confidential significant new use designation can currently file a *bona fide* inquiry to determine whether a specific use is a significant new use and EPA's amendments for future *bona fide* inquiries. In identifying the significant new use in subpart E for certain previously issued SNURs where the use described in the premanufacture notice was not claimed confidential, EPA cited 40 CFR 721.80(j) and included the PMN use described in the premanufacture notice in parentheses. EPA has received public comments in response to proposed SNURs and pre-notice inquiries for SNURs stating that manufacturers and processors subject to SNURs find it confusing when EPA cites 40 CFR 721.80(j) and then identifies the PMN use in parentheses. These comments and inquiries have explained that when EPA cites the new use this way it appears as though the significant new use is the use in the parentheses, where the significant new use is actually use other than the use in parentheses.

To better identify the significant new use, EPA has changed this procedure to only cite 40 CFR 721.80(j) when the use described in the PMN is confidential. When the use described in the PMN is not confidential, EPA intends to identify the significant new use in a new chemical SNUR by describing the use, such as in the following example: "A significant new use is any use other than as a pesticide intermediate." (This example was published in the direct final SNUR issued on February 12, 2014 (79 FR 8291) (Ref. 10) and is codified in subpart E at 40 CFR 721.10718.)

D. Changes to 40 CFR 721.91, Computation of estimated surface water concentrations:

Instructions.

When EPA issues a new chemical SNUR citing the significant new uses described in 40 CFR 721.90 (a)(4), (b)(4), and (c)(4), the SNUR requires significant new use notification if the results of the equation for computation of estimated surface water concentrations in 40 CFR 721.91 exceed the level specified for that SNUR in subpart E. The equation estimates surface water concentrations based on the amount of a chemical substance released from industrial

processes and the flows of the water body. The current equation does not take into consideration amounts of a chemical substance released to a surface water after control technology such as wastewater treatment. As proposed, EPA is revising this requirement to allow manufacturers and processors to account for reductions in surface water concentrations resulting from wastewater treatment. 40 CFR 721.91 contains instructions for the computation of estimated surface water concentrations according to the equation specified in 40 CFR 721.90 (a)(4), (b)(4), and (c)(4). EPA is revising the instructions at 40 CFR 721.91 to allow for a certain percentage of removal of a chemical substance from wastewater after undergoing control technology, applicable to the requirements at 40 CFR 721.90. EPA has previously allowed surface water concentrations to be calculated with a consideration of wastewater treatment in certain SNURs by adding regulatory text to individual rules. This change to 40 CFR 721.91 will make the consideration of control technology part of the calculations for the equation specified in 40 CFR 721.90 when cited in subpart E for a specific chemical substance. EPA will cite the control technology and the percentage removal for SNURs in subpart E, based on EPA's assessment of the effectiveness of the control technology for the specific chemical substance. The most common form of control technology in new chemical SNURs is wastewater treatment. However, EPA will not identify a percentage of removal from wastewater for every chemical substance subject to a SNUR with the significant new use specified in 40 CFR 721.90 (a)(4), (b)(4), and (c)(4). Rather, EPA, when appropriate, will identify an applicable removal percentage when issuing SNURs. The revised provisions will apply only when a removal percentage has been identified in the SNUR. This change does not apply to existing SNURs where a removal percentage has not been identified.

Due to questions and comments from manufacturers and processors expressing confusion around the meaning of the phrase "predictable or purposeful release" at 40 CFR 721.90, EPA is making changes to clarify the scope of the term. The phrase is used to qualify significant new uses pertaining to releases to water in 40 CFR 721.90. As described in the April 29, 1987 proposed rule, Proposed General Provisions for New Chemicals Follow-up (52 FR 15608) (Ref.

11), the phrase “predictable or purposeful” does not include releases where emergency conditions exist and significant new use notification is not possible. Therefore, routine or repeated activity that results in releases to water or non-routine releases to water that are not due to emergency conditions are included in the term “predictable or purposeful.” EPA does not intend the phrase “predictable or purposeful release” to limit the agency’s strict liability authority under the statute.

E. Changes to 40 CFR 721.11, Applicability determination when the specific chemical identity is confidential.

Certain new chemical SNURs have a significant new use designation that is based on confidential business information (CBI) contained in the PMN and therefore, not disclosed in the published SNUR. Currently, for each SNUR containing a significant new use designation considered to be CBI, that SNUR cross-references the *bona fide* procedure in the specific SNUR in subpart E for 40 CFR 721.1725. Under the *bona fide* procedures, a manufacturer or processor may request EPA to determine whether a specific use would be a significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule.

When the chemical identity in a SNUR is CBI, 40 CFR 721.11 provides a means by which *bona fide* submitters can determine whether their substance is subject to the SNUR. However, as described in the previous paragraph, chemical identity is not the only information contained in a SNUR that may be claimed as CBI. EPA is modifying the *bona fide* procedure in 40 CFR 721.11 of subpart A so that it applies to all SNURs containing any CBI, including the significant new use. EPA finds it would be more efficient to have a *bona fide* procedure for

determining confidential significant new uses in subpart A rather than referencing 40 CFR 721.1725(b)(1) each time EPA issues a SNUR containing a significant new use designation containing CBI. In addition, EPA is modifying the *bona fide* procedure that allows EPA to disclose the confidential significant new use designations to a manufacturer or processor who has established a *bona fide* intent to manufacture (including import) or process a particular chemical substance.

F. Changes for submission of SDS(s) with PMNs, SNUNs, Low Volume Exemptions (LVEs), Low Release and Exposure Exemptions (LoREXs), and Test Marketing Exemption (TME) Applications.

EPA is revising requirements in 40 CFR 720.38, 720.45, and 40 CFR 723.50 to require that any safety data sheet (SDS) already developed, even if in draft form, either to comply with OSHA requirements or for other purposes, must also be submitted as part of any notification or exemption application (PMN, SNUN, LVE, LoREX, or TME) under section 5 of TSCA. Many submitters already submit available SDSs as part of their submission and the information contained in SDSs is often useful for EPA's assessments of chemicals. This revision would not require submitters to develop an SDS. It only requires a submitter to submit an already-developed SDS as part of a notification under TSCA section 5, to the extent the SDS is known or reasonably ascertainable by the submitter.

G. Fixing typographical errors and other non-substantive changes.

EPA is correcting several typographical errors and more accurately applying the terms manufacture, manufacturer, and manufacturing to the regulatory text of sections 40 CFR parts 720, 721, and 723.

IV. References

The following is a list of the documents that are specifically referenced in this document. The docket includes these documents, as well as other information considered by EPA that are not listed below, including documents that are referenced within the documents that are included

in the docket. For assistance in locating docket items, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Significant New Uses of Chemical Substances; Updates to the Hazard Communication Program and Regulatory Framework; Minor Amendments to Reporting Requirements for Premanufacture Notices; Proposed Rule. *Federal Register* (81 FR 49598, July 28, 2016) (FRL-9944-47).

2. OSHA. OSHA Revised Hazard Communication Standard; Final Rule. *Federal Register* (77 FR 17574, March 26, 2012).

3. EPA. Economic Analysis for Final Rule Amendments to Part 721 – Modifications to General and Specific Requirements in the SNUR Framework – Significant New Uses of Chemical Substances. May 2022.

4. EPA. Response to Comments on the Proposed Rule Significant New Uses of Chemical Substances; Updates to the Hazard Communication Program and Regulatory Framework; Minor Amendments to Reporting Requirements for Premanufacture Notices. May 2022.

5. NIOSH. Respiratory Protection Devices; Final Rule. *Federal Register* (60 FR 30355, June 8, 1995).

6. OSHA. Respiratory Protection; Final Rule. *Federal Register* (63 FR 1152, January 8, 1998).

7. OSHA. Assigned Protection Factors; Final Rule. *Federal Register* (71 FR 50121, August 24, 2006).

8. EPA. Chart comparing assigned protection factors of current respirator classes with older respirator requirements.

9. EPA. Significant New Use Rules on Certain Chemical Substances; Final Rule. *Federal Register* (78 FR 32810, June 26, 2013) (FRL-9390-6).

10. EPA. Significant New Use Rules on Certain Chemical Substances; Direct Final Rule. *Federal Register* (79 FR 8291, February 12, 2014) (FRL- 9903-70).

11. EPA. Significant New Uses of Chemical Substances; General Provisions for New Chemical Follow-up; Proposed Rule. *Federal Register* (52 FR 15594, April 29, 1987) (FRL-3153-6).

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

OMB has approved the information collection activities contained in this rule pursuant to the PRA (44 U.S.C. 3501 *et seq.*) and has assigned OMB control number 2070-0012 (EPA ICR No. 574.15). This action does not impose any new requirements requiring additional OMB approval under the PRA. Estimates presented below reflect minor incremental changes associated with the rule as presented in the Economic Analysis (Ref. 3).

Respondents/affected entities: Certain manufacturers (including importers) and processors (see Unit I.A.).

Respondent's obligation to respond: Mandatory under TSCA section 5. This rule does not change the obligation that is contained in individual chemical specific SNURs.

Estimated number of respondents: 1,226.

Frequency of response: On occasion, i.e., upon submission of a SNUN pursuant to individual chemical specific SNURs.

Total estimated incremental burden: 1,585 hours (for the first year), then 486 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated incremental cost: \$ 94,731 (for the first year), then \$ 54,029 (per year).

This includes \$0 annualized capital or operation & maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* In making this determination, EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities and that the Agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities. The Agency's basis is briefly summarized here and is detailed in the Economic Analysis (Ref. 3).

EPA has observed only a small proportion of SNUNs submitted by self-declared small businesses. To the extent that the percentage of small firms abiding by a SNUR is similar to the percentage of small firms submitting SNUNs, it is unlikely that a substantial number of small entities would be affected by this final rule's changes to SNUR requirements. Similarly, for TSCA section 5 notices, assuming that a similar small proportion of small firms are submitting all notices, it is likewise unlikely that substantial number of small entities would be affected by this final rule's changes.

EPA also concludes that the steady state incremental per-firm costs of complying with the rule, estimated to range from \$23-\$109 per firm (Ref. 3), are low compared to the cost of developing and marketing a chemical.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and will not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments. Based on EPA's experience with

proposing and finalizing SNURs, state, local, and tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any state, local, or tribal government would be impacted by this rulemaking. EPA concludes that this rule is not expected to result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more (when adjusted annually for inflation) in any one year. Accordingly, this rule is not subject to the requirements of UMRA sections 202, 203, or 205. The Economic Analysis (Ref. 3) for this action is summarized in Unit I.E. and is available in the docket.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14008: Tackling the Climate Crisis at Home and Abroad

In accordance with Executive Orders 12898 (59 FR 7629, February 16, 1994) and 14008 (86 FR 7619, January 27, 2021), EPA finds that this action will not result in disproportionately high and adverse human health, environmental, climate-related, or other cumulative impacts on disadvantaged communities because this action does not establish an environmental health or safety standard.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5. U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Parts 720, 721, and 723

Environmental protection, Chemicals, Hazardous materials, Recordkeeping, and Reporting Requirements.

Dated: **June 15, 2022.**

Denise Keehner

Director, Office of Pollution Prevention and Toxics.

Therefore, for the reasons set forth in the preamble, 40 CFR chapter I is amended as follows:

PART 720-- PREMANUFACTURE NOTIFICATION

1. The authority citation for part 720 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2613.

§ 720.1 [Amended]

2. Amend § 720.1 by removing the phrase “and importers”.

3. In § 720.3:

a. Revise paragraph (r) introductory text and paragraph (r)(1);

b. Revise paragraph (s) introductory text and paragraph (s)(2); and

c. Revise paragraph (cc).

The revisions read as follows:

§ 720.3 Definitions.

* * * * *

(r) *Manufacture for commercial purposes* means:

(1) To manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes, among other things, “manufacture” of any amount of a chemical substance or mixture:

* * * * *

(s) *Manufacture solely for export* means to manufacture for commercial purposes a chemical substance solely for export from the United States under the following restrictions on activities in the United States:

* * * * *

(2) The manufacturer and any person to whom the substance is distributed for purposes of export or processing solely for export (as defined in § 721.3 of this chapter), may not use the substance except in small quantities solely for research and development in accordance with §

720.36.

* * * * *

(cc) *Small quantities solely for research and development* (or “small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product”) means quantities of a chemical substance manufactured or processed or proposed to be manufactured or processed solely for research and development that are not greater than reasonably necessary for such purposes.

* * * * *

§ 720.30 [Amended]

4. Amend § 720.30 by

- a. Removing the phrase “or imported” wherever it appears; and
- b. In paragraph (h)(7)(i) removing the word “intended” and adding in its place “intended”.

§ 720.36 [Amended]

5. Amend § 720.36 by removing the phrases “or imported”, “or importer”, “or imports” wherever they appear in the section.

6. Amend § 720.38 by:

- a. Removing the phrase “or import” wherever it appears in the section; and
- b. Adding paragraph (b)(7).

The addition reads as follows:

§ 720.38 Exemptions for test marketing.

* * * * *

(b)(7) Any safety data sheet already developed for the chemical substance, including draft safety data sheets.

* * * * *

§ 720.40 [Amended]

7. Amend § 720.40 by removing the phrases “or import” and “or importer” wherever they appear.

8. Amend § 720.45 by:

- a. In paragraph (e), removing the phrase “or imported” wherever it; and
- b. Adding paragraph (i).

The addition reads as follows:

§ 720.45 Information that must be included in the notice form.

* * * * *

(i) Any safety data sheet already developed for the new chemical substance, including draft safety data sheets.

* * * * *

§ 720.57 [Amended]

9. In § 720.57 amend paragraph (a) by removing the word “chemcial” and adding in its place “chemical”.

§ 720.78 [Amended]

10. Amend § 720.78 by:

- a. In paragraph (b)(1) introductory text, removing the phrase “or import”;
- b. In paragraph (b)(1)(iv), removing the word “manufacturer” and adding in its place “manufacturer”;
- c. In paragraph (b)(2), removing the phrase “or imports” wherever it appears; and
- d. In paragraph (c) remove the phrase “or import”.

§ 720.85 [Amended]

11. Amend § 720.85 by:

- a. Removing the phrases “or import” and “or importing” wherever they appear;
- b. In paragraph (b)(1):
 - i. Removing the phrase “or imported”;

- ii. Removing the word “indentify” and adding in its place “identity”;
- c. In paragraph (b)(2)(i):
 - i. Removing the word “manufactures” and adding in its place “manufactures”;
 - ii. Removing the phrase “or imports”; and
- d. In paragraph (b)(3)(iv)(D) remove the phrase “on imported”.

§ 720.90 [Amended]

- 12. Amend § 720.90 by removing the phrase “or import” wherever it appears.

§ 720.102 [Amended]

- 13. Amend § 720.102 by removing the phrase “or import” wherever it appears.

§ 720.120 [Amended]

- 14. In § 720.120 amend paragraph (b) by:
 - a. Removing the phrase “or imports”; and
 - b. Removing the word “requied” and adding in its place “required”.

PART 721--SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

- 15. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

- 16. Amend part 721 by:

- a. Removing the acronym “MSDS” everywhere it appears and adding in its place the acronym “SDS”;
- b. Removing the acronym “MSDSs” everywhere it appears and adding in its place the acronym “SDSs”; and
- c. Removing the phrase “material safety” everywhere it appears and adding in its place the word “safety”.

§ 721.1 [Amended]

- 17. In § 721.1 amend paragraph (a) by removing the phrase “manufacturers, importers and processors” and adding in its place “manufacturers and processors”.

18. Amend § 721.3 by:

a. Revising the definitions of “Customer,” “Employer,” “Non-industrial use,” and “Recipient;” and

b. Removing the definition of “MSDS”; and

c. Adding in alphabetical order the definition for “Safety Data Sheet.”

The revisions and addition read as follows:

§ 721.3 Definitions.

* * * * *

Customer means any person to whom a manufacturer or processor distributes any quantity of a chemical substance, or of a mixture containing the chemical substance, whether or not a sale is involved.

* * * * *

Employer means any manufacturer, processor, or user of chemical substances or mixtures.

* * * * *

Non-industrial use means use other than at a facility where chemical substances or mixtures are manufactured or processed.

* * * * *

Recipient means any person who purchases or otherwise obtains a chemical substance directly from a person who manufactures or processes the substance.

* * * * *

Safety Data Sheet (SDS) means written or printed material concerning a hazardous chemical substance that is prepared as required under § 721.72(c).

* * * * *

§ 721.5 [Amended]

19. Amend § 721.5 by:

- a. Removing the phrase “manufacturer, importer, or processor” everywhere it appears, and adding in its place the phrase “manufacturer or processor”;
- b. Removing the phrase “manufacture, import, or process” everywhere it appears, and adding in its place the phrase “manufacture or process”; and
- c. In paragraph (d)(1)(iii), removing the word “recepient’s” and adding in its place “recipient’s”.

§ 721.11 [Amended]

20. Amend § 721.11 by:

- a. Removing the phrase “manufacturer, importer, or processor” everywhere it appears, and adding in its place the phrase “manufacturer or processor”;
- b. Removing the phrase “manufacture, import, or process” everywhere it appears, and adding in its place the phrase “manufacture or process”;
- c. Revising the section heading and paragraphs (a) and (e) through (g).

The revisions read as follows:

§ 721.11 Applicability determination when the specific chemical identity is confidential.

(a) A person who intends to manufacture or process a chemical substance which is subject to a significant new use rule in subpart E of this part may ask EPA whether the substance or a proposed use is subject to the requirements of this part if that substance is described by a generic chemical name or if the significant new use is confidential and therefore not described specifically in the rule. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture or process the chemical substance for commercial purposes.

* * * * *

(e) If the manufacturer or processor has shown a *bona fide* intent to manufacture or process the substance and has provided sufficient unambiguous chemical identity information to enable EPA to make a conclusive determination as to the identity of the substance, EPA will

inform the manufacturer or processor whether the chemical substance is subject to this part and, if so, which section in subpart E of this part applies, and identify any confidential significant new use designations.

(f) A disclosure to a person with a *bona fide* intent to manufacture or process a particular chemical substance that the substance is subject to this part or of confidential significant new use designations will not be considered public disclosure of confidential business information under section 14 of the Act.

(g) EPA will answer an inquiry on whether a particular chemical substance is subject to this part or identify and confidential significant new uses within 30 days after receipt of a complete submission under paragraph (b) of this section.

§ 721.25 [Amended]

21. Amend § 721.25 by:

a. In paragraph (a) removing the phrase “manufacture, import, or processing” and add in its place the phrase “manufacture or processing”.

b. In paragraph (d) removing the phrase “manufacture, import, or process” and add in its place the phrase “manufacture or process”.

§ 721.30 [Amended]

22. Amend § 721.30 by:

a. Removing the phrase “manufacture, import, or processing” everywhere it appears and adding in its place the phrase “manufacture or processing”;

b. In paragraph (a) remove the phrase “manufacture, import, or process” and add in its place the phrase “manufacture or process”.

§ 721.35 [Amended]

23. Amend § 721.35 by:

a. Removing the phrase “manufactured, imported, or processed” everywhere it appears and adding in its place the phrase “manufactured or processed”; and

b. In paragraph (f)(1) removing the phrase “manufacture, import, or processing” and adding in its place the phrase “manufacture or processing”.

§ 721.45 [Amended]

24. Amend § 721.45 by removing the phrase “manufactures, imports, or processes” everywhere it appears and adding in its place the phrase “manufactures or processes”.

§ 721.47 [Amended]

25. Amend § 721.47 by:

a. Removing the phrase “manufactures, imports, or processes” everywhere it appears and adding in its place the phrase “manufactures or processes”;

b. Removing the phrase “manufacturer, importer, or processor” everywhere it appears and add in its place the phrase “manufacturer or processor”; and

c. Removing the phrase “manufacture, import, or process” everywhere it appears and adding in its place the phrase “manufacture or process”.

26. Amend § 721.63 by:

a. Revising paragraphs (a) introductory text, (a)(4) and (a)(5) introductory text;

b. Adding paragraphs (a)(5)(xvi) through (a)(5)(li);

c. Revising paragraph (a)(6) introductory text;

d. Adding paragraphs (a)(6)(vii) through (a)(6)(ix), (a)(7) and (a)(8); and

e. Revising paragraph (c)(2).

The revisions and additions read as follows:

§ 721.63 Protection in the workplace.

(a) Whenever a substance is identified in subpart E of this part as being subject to this section, any manner or method of manufacturing (including importing) or processing associated with any use of the substance is considered a significant new use unless a program is established whereby:

* * * * *

(4) Each person who is reasonably likely to be exposed to the chemical substance by inhalation in the work area in one or more of the forms listed in paragraph (a)(6) of this section and cited in subpart E of this part for the chemical substance, is provided with, and is required to wear, at a minimum, a NIOSH- approved respirator from one of the categories listed in paragraph (a)(5) of this section, and the respirator is used in accordance with 29 CFR 1910.134 and 42 CFR part 84.

(5) The following NIOSH-certified respirators meet the requirements for paragraph (a)(4) of this section:

* * * * *

(xvi) NIOSH-certified N100 (if oil aerosols absent), R100, or P100 filtering facepiece respirator. (APF =10).

(xvii) NIOSH-certified air-purifying half-mask respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. (APF =10).

(xviii) NIOSH-certified air-purifying half mask respirator equipped with appropriate gas/vapor cartridges. (APF =10).

(xix) NIOSH-certified air-purifying half-mask respirator equipped with appropriate gas/vapor cartridges in combination with N100, R100, or P100 filters or an appropriate canister incorporating N100, R100, or P100 filters. (APF =10).

(xx) NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask. (APF =10).

(xxi) NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half mask. (APF =10).

(xxii) NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and HEPA filters. (APF =25).

(xxiii) NIOSH-certified powered air-purifying respirator with a hood or helmet equipped with appropriate gas/vapor cartridges. (APF =25).

(xxiv) NIOSH-certified powered air-purifying respirator with a hood or helmet and with appropriate gas/vapor cartridges in combination with HEPA filters. (APF =25).

(xxv) NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece and HEPA filters. (APF =25).

(xxvi) NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece with appropriate gas/vapor cartridges. (APF =25).

(xxvii) NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece with appropriate gas/vapor cartridges in combination with HEPA filters. (APF =25).

(xxviii) NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet. (APF =25).

(xxix) NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece. (APF =25).

(xxx) NIOSH-certified air-purifying full facepiece respirator equipped with N100, R-100, or P-100 filter(s). (APF =50).

(xxxi) NIOSH-certified air-purifying full facepiece respirator equipped with appropriate gas/vapor cartridges or canisters. (APF =50).

(xxxii) NIOSH-certified air-purifying full facepiece respirator equipped with appropriate gas/vapor cartridges in combination with N100, R100, or P100 filters or an appropriate canister incorporating N100, R100, or P100 filters. (APF =50).

(xxxiii) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting half mask and HEPA filters. (APF =50).

(xxxiv) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting half mask and appropriate gas/vapor cartridges or canisters. (APF =50).

(xxxv) NIOSH-certified powered air-purifying respirator with a tight-fitting half mask and appropriate gas/vapor cartridges in combination with HEPA filters. (APF =50).

(xxxvi) NIOSH-certified pressure-demand or other positive pressure mode supplied-air

respirator equipped with a half-mask. (APF =50).

(xxxvii) NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece. (APF =50).

(xxxviii) NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting half mask. (APF =50).

(xxxix) NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece. (APF =50).

(xl) NIOSH-certified powered air purifying full facepiece respirator equipped with HEPA filters. (APF =1,000).

(xli) NIOSH-certified powered air purifying full facepiece respirator equipped with appropriate gas/vapor cartridges. (APF =1,000).

(xlii) NIOSH-certified powered air purifying full facepiece respirator equipped with appropriate gas/vapor cartridges in combination with HEPA filters. (APF =1,000).

(xliii) NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and N100, R100, or P100 filters *with evidence demonstrating protection level of 1,000 or greater*. See 40 CFR 721.63(a)(5)(li). (APF =1,000).

(xliv) NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and appropriate gas/vapor cartridges *with evidence demonstrating protection level of 1,000 or greater*. See 40 CFR 721.63(a)(5)(li). (APF =1,000).

(xlv) NIOSH-certified powered air-purifying respirator with a loose-fitting hood or helmet that is equipped with an appropriate gas/vapor cartridge in combination with HEPA filters *with evidence demonstrating protection level of 1,000 or greater*. See 40 CFR 721.63(a)(5)(li). (APF =1,000).

(xlvi) NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece. (APF =1,000).

(xlvii) NIOSH-certified continuous flow supplied-air respirator equipped with a hood or

helmet *with evidence demonstrating protection level of 1,000 or greater*. See 40 CFR

721.63(a)(5)(li). (APF =1,000).

(xlviii) NIOSH-certified pressure-demand supplied-air respirator equipped with a full facepiece. (APF =1,000).

(xlix) NIOSH-certified pressure-demand or other positive-pressure mode (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece. (APF =10,000).

(l) If one of the respirators in paragraph (a)(5)(i) through (a)(5)(xv) is cited for a substance identified in subpart E an employer may substitute a respirator from paragraphs (a)(5)(xvi) through (a)(5)(xlix) as long as its assigned protection factor is equal to or greater than the respirator cited in subpart E for that substance.

(li) Without testing data that demonstrates a level of protection of 1,000 or greater, all air purifying respirators and supplied air respirators with helmets/hoods are to be treated as loose-fitting facepiece respirators with an APF of 25.

(6) When cited in subpart E of this part for a substance, the following airborne form(s) of the substance, in combination or alone, are referenced by paragraphs (a)(1) and (4) of this section:

* * * * *

(vii) Particulate or aerosol (solids or liquid droplets suspended in a gas, e.g., dust, fume, mist, smoke).

(viii) Gas/vapor.

(ix) Combination particulate and gas/vapor (gas and liquid/solid physical forms are both present, e.g., particulates and acid gases or particulates and organic vapors).

(7) Where people are reasonably likely to have dermal or eye exposure to the chemical substance in the work area, either through direct handling of the substance, or through contact with surfaces on which the substance may exist, or because the substance becomes airborne in

the form listed in paragraph (a)(6) of this section, and the form is cited in subpart E of this part for the chemical substance, engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be implemented to prevent exposure, where feasible. Where engineering, work practice, and administrative controls are not feasible or dermal or eye exposure is still reasonably likely, each person who is reasonably likely to be exposed to the chemical substance by dermal or eye exposure must be provided with, and is required to wear, personal protective equipment (PPE) to prevent dermal or eye exposure to the substance. Refer to 29 CFR 1910.132 and 29 CFR 1910.133 for requirements on selection and use of PPE.

(8) Where each person who is reasonably likely to be exposed to the chemical substance by inhalation in the work area in one or more of the forms listed in paragraph (a)(6) of this section and cited in subpart E of this part for the chemical substance, engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. When engineering, work practice, and administrative controls are not feasible or inhalation exposure is still reasonably likely, each person who is reasonably likely to be exposed to the chemical substance by inhalation in the work area in one or more of the forms listed in paragraph (a)(6) of this section and cited in subpart E of this part for the chemical substance, must be provided with, and is required to wear, a NIOSH- certified respirator from one of the categories listed in paragraph (a)(5) of this section. Refer to 29 CFR 1910.134 and 42 CFR part 84 for requirements on the selection, use, and maintenance of respirators, including establishing respiratory protection program, medical determination, and other administrative and programmatic requirements for respiratory protection.

* * * * *

(c) * * *

(2) If, after receiving a statement of assurance from a recipient under paragraph (c)(1)(ii) of this section, a manufacturer or processor has knowledge that the recipient is engaging in an activity that is not consistent with the implementation of the program specified in paragraph (a) of this section, that person is considered to have knowledge that the person is engaging in a significant new use and is required to follow the procedures in § 721.5(d).

27. Amend § 721.72 by:

- a. Revising the introductory text;
- b. Revising paragraphs (a) introductory text and (a)(1);
- c. Revising paragraphs (b)(5), (c)(5), (c)(7) and (c)(9);
- d. Revising paragraphs (g)(1) and (2);
- e. Revising paragraphs (g)(3)(i) through (g)(3)(ii) and adding paragraph (g)(3)(iii);
- f. Revising paragraphs (g)(4)(i) through (g)(4)(iii) and adding paragraph (g)(4)(iv);
- g. Revising paragraphs (h)(1)(ii), (h)(1)(iii)(A) through (h)(1)(iii)(E) and adding paragraphs (h)(1)(iii)(F) through (h)(1)(iii)(H);
- h. Revising paragraphs (h)(1)(iv), (h)(1)(v)(A) through (h)(1)(v)(C) and adding paragraph (h)(1)(v)(D);
- i. Revising paragraphs (h)(2)(ii), (h)(2)(iii) and (h)(2)(iv);
- j. Revising paragraphs (h)(2)(v)(A) through (h)(2)(v)(C) and adding paragraph (h)(2)(v)(D);
- k. Adding paragraphs (i) and (j).

The additions and revisions as follows:

§ 721.72 Hazard communication program.

Whenever a substance is identified in subpart E of this part as being subject to this section, a significant new use of that substance is any manner or method of manufacture (including import) or processing associated with any use of that substance without establishing a hazard communication program as described in this section. Paragraphs (a) through (h) of this

section apply to SNURs issued before [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Paragraphs (i) and (j) of this section apply to SNURs issued on or after [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Any person subject to the requirements of paragraphs (a) through (h) of this section have the option of following the requirements of paragraph (i) of this section or using the statements specified in paragraphs (g) or (h) of this section.

(a) *Written hazard communication program.* Each employer shall develop and implement a written hazard communication program for the substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, SDSs, and other forms of warning material will be satisfied. The employer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The employer may rely on an existing hazard communication program, including an existing program established under the Occupational Health and Safety Administration (OSHA) Hazard Communication Standard in 29 CFR 1910.1200 of 2012 to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this paragraph. The written program shall include the following:

(1) A list of each substance identified in subpart E of this part as subject to this section known to be present in the work area. The list must be maintained in the work area and must use the identity provided on the appropriate SDS for each substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas.

* * * * *

(b) * * *

(5) If the label or alternative form of warning is to be applied to a mixture containing a substance identified in subpart E of this part as subject to this section in combination with another substance identified in subpart E of this part and/or a substance defined as a “hazardous chemical” under the Occupational Safety and Health Administration (OSHA) Hazard

Communication Standard (29 CFR 1910.1200), the employer may prescribe on the label, SDS, or alternative form of warning, the measures to control worker exposure or environmental release which the employer determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under subpart E of this part, the employer must seek a determination of equivalency for such alternative control measures pursuant to § 721.30 before prescribing them under this paragraph (b)(5).

* * * * *

(c) * * *

(5) If the employer becomes aware of any significant new information regarding the hazards of the substance or ways to protect against the hazards, this new information must be added to the SDS within 3 months from the time the employer becomes aware of the new information. If the substance is not currently being manufactured, processed, or used in the employer's workplace, the employer must add the new information to the SDS before the substance is reintroduced into the workplace.

* * * * *

(7) The employer must maintain a copy of the SDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas. (Easy and immediate electronic access and other alternatives to maintaining paper copies of the safety data sheets are permitted as long as complete and accurate versions of the SDS are available immediately to employees in each workplace by such options.)

* * * * *

(9) The SDS must be in English; however, the information may be repeated in other languages.

* * * * *

(g) * * *

(1) Human health hazard statements:

(i) Causes skin irritation.

(ii) Respiratory complications. (You may also use paragraph (g)(1)(x) of this section for this designation.).

(iii) Central nervous system effects. (You may also use paragraph (g)(1)(xi) of this section for this designation but you must include this specific effect.)

(iv) Internal organ effects. (You may also use paragraph (g)(1)(xi) of this section for this designation.)

(v) Birth defects. (You may also use paragraph (g)(1)(xii) of this section for this designation but you must include this specific effect.)

(vi) Reproductive effects. (You may also use paragraph (g)(1)(xii) of this section for this designation but you must include this specific effect.)

(vii) May cause cancer.

(viii) Immune system effects. (You may also use paragraph (g)(1)(xi) of this section for this designation but you must include this specific effect.)

(ix) Developmental effects. (You may also use paragraph (g)(1)(xii) of this section for this designation but you must include this specific effect.)

(x) May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(xi) May cause damage to organs (state all organs identified in subpart E of this part for this substance) through prolonged or repeated exposure.

(xii) May damage fertility or the unborn child (state specific effect identified in subpart E of this part for this substance).

(xiii) May cause an allergic skin reaction.

(xiv) Causes eye irritation.

(2) Human health hazard precautionary statements:

(i) Avoid skin contact. (You may also use paragraph (g)(2)(vi) of this section for this

designation.)

(ii) Avoid breathing substance. (You may also use paragraph (g)(2)(viii) of this section for this designation.)

(iii) Avoid ingestion.

(iv) Use respiratory protection. (You may also use paragraph (g)(2)(vii) of this section for this designation.)

(v) Use skin protection. (You may also use paragraph (g)(2)(vi) of this section for this designation.)

(vi) Wear protective gloves/protective clothing/eye protection/face protection.
(Chemical manufacturer or distributor to specify type of equipment, as required.)

(vii) Wear respiratory protection. (Chemical manufacturer or distributor to specify equipment as required.)

(viii) Avoid breathing dust/fume/gas/mist/vapors/spray. (Chemical manufacturer or distributor to specify applicable conditions.)

(3) * * *

(i) Toxic to fish. (You may also use paragraph (g)(3)(iii) of this section for this designation.)

(ii) Toxic to aquatic organisms. (You may also use paragraph (g)(3)(iii) of this section for this designation.)

(iii) Toxic to aquatic life.

(4) * * *

(i) Disposal restrictions apply. (You may also use paragraph (g)(4)(iv) of this section for this designation.)

(ii) Spill clean-up restrictions apply. (You may also use paragraph (g)(4)(iv) of this section for this designation.)

(iii) Do not release to water. (You may also use paragraph (g)(4)(iv) of this section for

this designation.)

(iv) Dispose of contents/container to ... (Specify disposal requirements in subpart E of this part and whether they apply to contents, container or both.)

* * * * *

(h) * * *

(ii) *Human health hazard statements.* (A) Causes skin irritation.

(B) Respiratory complications. (You may also use paragraph (h)(1)(ii)(J) of this section for this designation.)

(C) Central nervous system effects. (You may also use paragraph (h)(1)(ii)(K) of this section for this designation but you must include this specific effect.)

(D) Internal organ effects. (You may also use paragraph (h)(1)(ii)(K) of this section for this designation.)

(E) Birth defects. (You may also use paragraph (h)(1)(ii)(L) of this section for this designation but you must include this specific effect.)

(F) Reproductive effects. (You may also use paragraph (h)(1)(ii)(L) of this section for this designation but you must include this specific effect.)

(G) Cancer.

(H) Immune system effects. (You may also use paragraph (h)(1)(ii)(K) of this section for this designation but you must include this specific effect.)

(I) Developmental effects. (You may also use paragraph (h)(1)(ii)(L) of this section for this designation but you must include this specific effect.)

(J) May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(K) May cause damage to organs (state all organs identified in subpart E of this part for this substance) through prolonged or repeated exposure.

(L) May damage fertility or the unborn child (state specific effect identified in subpart E of this part for this substance).

(M) May cause an allergic skin reaction.

(N) Causes eye irritation.

(iii) *Human health hazard precautionary statements.* (A) Avoid skin contact. (You may also use paragraph (h)(1)(iii)(F) of this section for this designation.)

(B) Avoid breathing substance. (You may also use paragraph (h)(1)(iii)(H) of this section for this designation.)

(C) Avoid ingestion.

(D) Use respiratory protection. (You may also use paragraph (h)(1)(iii)(G) of this section for this designation.)

(E) Use skin protection. (You may also use paragraph (h)(1)(iii)(F) of this section for this designation.)

(F) Wear protective gloves/protective clothing/eye protection/face protection. (Chemical manufacturer or distributor to specify type of equipment, as required.)

(G) Wear respiratory protection. (Chemical manufacturer or distributor to specify equipment as required.)

(H) Avoid breathing dust/fume/gas/mist/vapors/spray. (Chemical manufacturer or distributor to specify applicable conditions.)

(iv) *Environmental hazard statements.* (A) Toxic to fish. (You may also use paragraph (h)(1)(iv)(C) of this section for this designation.)

(B) Toxic to aquatic organisms. (You may also use paragraph (h)(1)(iv)(C) of this section for this designation.)

(C) Toxic to aquatic life.

(v) *Environmental hazard precautionary statements.* Notice to Users:

(A) Disposal restrictions apply. (You may also use paragraph (h)(1)(v)(D) of this section for this designation)

(B) Spill clean-up restrictions apply. (You may also use paragraph (h)(1)(v)(D) of this

section for this designation)

(C) Do not release to water. (You may also use paragraph (h)(1)(v)(D) of this section for this designation.)

(D) Dispose of contents/container to ... (Specify disposal requirements in subpart E of this part and whether they apply to contents, container or both.)

* * * * *

(2) * * *

(ii) *Human health hazard statements.* (A) Causes skin irritation.

(B) Respiratory complications. (You may also use paragraph (h)(2)(ii)(J) of this section for this designation.)

(C) Central nervous system effects. (You may also use paragraph (h)(2)(ii)(K) of this section for this designation but you must include this specific effect.)

(D) Internal organ effects. (You may also use paragraph (h)(2)(ii)(K) of this section for this designation.)

(E) Birth defects. (You may also use paragraph (h)(2)(ii)(L) of this section for this designation but you must include this specific effect.)

(F) Reproductive effects. (You may also use paragraph (h)(2)(ii)(L) of this section for this designation but you must include this specific effect.)

(G) May cause cancer.

(H) Immune system effects. (You may also use paragraph (h)(2)(ii)(K) of this section for this designation but you must include this specific effect.)

(I) Developmental effects. (You may also use paragraph (h)(2)(ii)(L) of this section for this designation but you must include this specific effect.)

(J) May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(K) May cause damage to organs (state all organs identified in subpart E of this part for this substance.) through prolonged or repeated exposure.

(L) May damage fertility or the unborn child (state specific effect identified in subpart E of this part for this substance).

(M) May cause an allergic skin reaction.

(N) Causes eye irritation.

(iii) *Human health hazard precautionary statements.* (A) Avoid skin contact. (You may also use paragraph (h)(2)(iii)(F) of this section for this designation.)

(B) Avoid breathing substance. (You may also use paragraph (h)(2)(iii)(H) of this section for this designation.)

(C) Avoid ingestion.

(D) Use respiratory protection. (You may also use paragraph (h)(2)(iii)(G) of this section for this designation.)

(E) Use skin protection. (You may also use paragraph (h)(2)(iii)(F) of this section for this designation.)

(F) Wear protective gloves/protective clothing/eye protection/face protection.
(Chemical manufacturer or distributor to specify type of equipment, as required.)

(G) Wear respiratory protection. (Chemical manufacturer or distributor to specify equipment as required.)

(H) Avoid breathing dust/fume/gas/mist/vapors/spray. (Chemical manufacturer or distributor to specify applicable conditions.)

(iv) *Environmental hazard statements.* (A) Toxic to fish. (You may also use paragraph (h)(2)(iv)(C) of this section for this designation.)

(B) Toxic to aquatic organisms. (You may also use paragraph (h)(2)(iv)(C) of this section for this designation.)

(C) Toxic to aquatic life.

(v) *Environmental hazard precautionary statements.* Notice to Users:

(A) Disposal restrictions apply. (You may also use paragraph (h)(2)(v)(D) of this section

for this designation.)

(B) Spill clean-up restrictions apply. (You may also use paragraph (h)(2)(v)(D) of this section for this designation.)

(C) Do not release to water. (You may also use paragraph (h)(2)(v)(D) of this section for this designation.)

(D) Dispose of contents/container to ... (Specify disposal requirements in subpart E of this part and whether they apply to contents, container or both.)

(i) *Written hazard communication program.* Each employer shall develop and implement a written hazard communication program for the substance in each workplace in accordance with 29 CFR 1910.1200.

(j) *Human health, environmental hazard, exposure, and precautionary statements.* In addition to the requirements for the hazard communication program specified in paragraph (i) of this section, whenever referenced in subpart E of this part for a substance, the following human health and environmental hazard, exposure, and precautionary statements shall appear as specified in paragraph (i) of this section.

(1) Human health hazard statements:

(i) Causes skin irritation.

(ii) May cause cancer.

(iii) Immune system effects.

(iv) Developmental effects.

(v) May cause allergy or asthma symptoms or breathing difficulties if inhaled.

(vi) May cause damage to organs (state all organs identified in subpart E of this part for this substance) through prolonged or repeated exposure.

(vii) May damage fertility or the unborn child (state specific effect identified in subpart E of this part for this substance).

(viii) May cause an allergic skin reaction.

(ix) Causes eye irritation.

(2) Human health hazard precautionary statements:

(i) Avoid ingestion.

(ii) Wear protective gloves/protective clothing/eye protection/face protection.

(Chemical manufacturer or distributor to specify type of equipment, as required.)

(iii) Wear respiratory protection.

(Chemical manufacturer or distributor to specify equipment as required.)

(iv) Avoid breathing dust/fume/gas/mist/vapors/spray.

(Chemical manufacturer or distributor to specify applicable conditions.)

(3) Environmental hazard statements: This substance may be:

(i) Toxic to aquatic life.

(ii) Very toxic to aquatic life.

(iii) Harmful to aquatic life.

(iv) Very toxic to aquatic life with long term effects.

(v) Toxic to aquatic life with long lasting effects.

(vi) Harmful to aquatic life with long lasting effects.

(vii) May cause long lasting harmful effects to aquatic life.

(4) Environmental hazard precautionary statements: Notice to users:

(i) Avoid release to the environment (if this is not the intended use.)

(ii) Collect spillage.

(iii) Dispose of contents/container to ... (Specify disposal requirements in subpart E of this part and whether they apply to contents, container or both.)

§ 721.80 [Amended]

28. Amend § 721.80 by:

a. Removing the phrases “or import”, “and importation” and “or importer” wherever they appear;

b. In paragraphs (p), (r), (s), (t) and (u) removing the word “manufacture” and adding in its place the word “manufacturing”.

§ 721.85 [Amended]

29. Amend § 721.85 by removing the word “supercede” wherever it appears and adding in its place “supersede”.

30. Amend § 721.91 by revising the introductory text and adding paragraph (a)(7) to read as follows:

§ 721.91 Computation of estimated surface water concentrations: Instructions.

These instructions describe the use of the equation specified in § 721.90(a)(4), (b)(4), and (c)(4) to compute estimated surface water concentrations which will result from release of a substance identified in subpart E of this part. The equation shall be computed for each site using the stream flow rate appropriate for the site according to paragraph (b) of this section, and the highest number of kilograms calculated to be released for that site on a given day according to paragraph (a) of this section. Two variables shall be considered in computing the equation, the number of kilograms released, and receiving stream flow.

(a) * * *

(7) When a substance is designated in subpart E of this part with a specific control technology and a percentage removal of the substance from wastewater resulting from use of the specified control technology, you may subtract that percentage from the highest expected daily release if that control technology is applied.

* * * * *

§ 721.100 [Amended]

31. In § 721.100, remove the phrase “manufacturers, importers, and processors” and add in its place “manufacturers and processors”.

32. Amend § 721.125 by revising the introductory text, and paragraphs (a), (c) and (j) to read as follows:

§ 721.125 Recordkeeping requirements.

At the time EPA adds a substance to subpart E of this part, EPA will specify appropriate recordkeeping requirements which correspond to the significant new use designations for the substance selected from subpart B of this part. Each manufacturer and processor of the substance shall maintain the records for 5 years from the date of their creation. In addition to the records specified in §721.40, the records whose maintenance this section requires may include the following:

(a) Records documenting the manufacturing volume of the substance and the corresponding dates of manufacture.

* * * * *

(c) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or processing to whom the manufacturer or processor directly sells or transfers the substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date.

* * * * *

(j) Records documenting compliance with any applicable disposal requirements under § 721.85, including the method of disposal, location of disposal sites, dates of disposal, and volume of the substance disposed. Where the estimated disposal volume is not known to or reasonably ascertainable by the manufacturer or processor, that person must maintain other records which demonstrate establishment and implementation of a program that ensures compliance with any applicable disposal requirements.

* * * * *

§ 721.160 [Amended]

33. Amend § 721.160 by:

- a. In paragraph (a)(1) removing the phrase “and import”.
- b. In paragraph (a)(2) removing the phrase “or import”.

PART 723--PREMANUFACTURE NOTIFICATION EXEMPTIONS

34. The authority citation for part 723 continues to read as follows:

Authority: 15 U.S.C. 2604.

35. Amend § 723.by:

a. Revising paragraph (a)(1) introductory text; and

b. Revising paragraph (e)(2)(xi)(A); and adding paragraph (e)(2)(xiii).

The revisions and addition read as follows:

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures

(a) * * * (1) This section grants an exemption from the premanufacture notice requirements of section 5(a)(1)(A) of the Toxic Substances Control Act (15 U.S.C. 2604(a)(1)(A)) for the manufacture of:

* * * * *

(e) * * *

(2) * * *

(xi) * * *

(A) The manufacturer intends to manufacture the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of this section.

* * * * *

(xiii) Safety Data Sheet (§ 720.45(i)).

* * * * *

§ 723.250 [Amended]

36. Amend § 723.250 as follows:

a. In table 1 to paragraph (e)(3) in the first note removing the phrase “composition,complex” and adding in its place “composition, complex”.

b. In paragraph (j)(1), removing the phrase “or import”.

[FR Doc. 2022-13324 Filed: 7/1/2022 8:45 am; Publication Date: 7/5/2022]